

Remarks

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and the reasons that follow.

A detailed listing of all claims that are, or were, in the application, irrespective of whether the claims remain under examination in the application, is presented with appropriately defined status identifiers.

Claims 1-11 and 13-27 are pending. Claims 1-11, 13, and 17 are rejected. Claims 14-26 were previously withdrawn.

Amendment to claims

Claim 1 is amended to delete PEG and block-copolymers of PEG with poly(butylene terephthalate) (PBT), which is PolyActive™, from the definition of the biobeneficial polymer recited in the claim.

Claim 7 is amended to delete poly(ethylene-glycol), poly(ethylene-glycol)-block-poly(butylene terephthalate)-block-poly(ethylene-glycol), poly(butylene terephthalate)-block-poly(ethylene-glycol)-block poly(butylene terephthalate), and poly(ethylene oxide-co-propylene oxide) from the definition of the biobeneficial polymer recited therein.

Claim 9 is amended to delete the term “cellulosics” from the definition of bioactive moiety recited therein.

Claim 13 is amended to indicate that cRGD is a cRGD peptide and that Rensten-NG is an antisense agent, both well known in the art.

References cited in information disclosure statements (IDSs)

The Examiner acknowledges Applicants' request for an initialed copy of IDS filed on March 4, 2004 as applied to references A60 and B22 and IDS filed on June 9, 2005 as applied to reference C1 but nonetheless fails to provide such a copy of IDSs. For the record, Applicants respectfully assume the Examiner has considered these references.

Rejections under 35 U.S.C. § 103(a)

On page 12 of the Action, the PTO maintains the rejection of claims 3, 5 and 6 under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. Patent No. 6,451,337 to Smith et al. (“Smith”), U.S. patent application publication No. 2002/0094440 by Llanos (“Llanos”), U.S. patent application publication No. 2005/0147643 by Hunter et al. (“Hunter”) in view of U.S. Patent No. 6,331,547 to Zhu et al. (“Zhu”) and U.S. Patent No. 7,011,812 to Griffiths et al. (“Griffiths”). Applicants respectfully disagree with these rejections.

To establish a *prima facie* case of obviousness, the PTO must provide evidence or well-grounded technical reasoning establishing that every feature of a claimed invention was part of the prior art or otherwise would have been known to an ordinary artisan prior to the time the claimed invention was made.

Claims 1-11, 13 and 27 all recite (1) a biologically beneficial polymer is selected from hyaluronic acid, phosphoryl choline, poly(ethylene oxide-co-propylene oxide), polyaspirin, and poly(ester amide) polymers, and (2) the biologically beneficial polymer being conjugated to a biologically active agent.

Smith discloses a medical device including chitosan and a nitric oxide donor. Smith, however, does not disclose a medical device having a bioactive agent conjugated to a polymer. Note, at page 6, last sentence of the first paragraph, the Examiner states that Applicants elected Polyactive polymer-bioactive agent conjugate as the specifics for examination. This appears to be a mistake by the Examiner. In fact, Applicants elected the polymer of claim 11 (poly(ester amide) as the biobeneficial polymer as the species for examination (see Applicants’ response to restriction requirement filed on April 27, 2007).

Llanos discloses a medical device including a fluoropolymer including Solef and a bioactive agent. However, Llanos does not disclose a biobeneficial polymer-bioactive agent conjugate.

Hunter discloses a medical device that includes a fibrosis-inducing agent. The device is to be used in an intervertebral disc space. There is no disclosure in Hunter a biobeneficial polymer-bioactive agent conjugate.

Zhu discloses a PEGylated SDZ-RAD.

Griffiths discloses drug/polymer conjugate for treating cancer. The polymer can be a polyamino acid, PEG, or another polymer described therein. However, Griffiths does not disclose a biobeneficial polymer-bioactive agent conjugate where the biobeneficial polymer is one of hyaluronic acid, phosphoryl choline, poly(ethylene oxide-co-propylene oxide), polyaspirin, and poly(ester amide) polymers.

Therefore, Zhu and Griffiths fail to make up the deficiencies of Smith, Llanos, and Hunter with respect to a biobeneficial polymer/bioactive agent conjugate as defined in the claims of the instant application. As such, Smith, Llanos, and Hunter in view of Zhu and Griffiths cannot make claims 1-11, 13, and 27 *prima facie* obvious under 35 U.S.C. §103(a). Claims 1-11, 13, and 27 are therefore patentably allowable over Smith, Llanos, and Hunter in view of Zhu and Griffiths under 35 U.S.C. §103(a).

Rejection under 35 U.S.C. §112, first paragraph

Claim 9 is rejected as lacking sufficient description for reciting the term “cellulosics” under 35 U.S.C. §112, 1st paragraph. Claim 9 no longer recites “cellulosics.” Applicants believe this rejection is now moot.

Rejection under 35 U.S.C. §112, second paragraph

Claims 1-11, 13 and 27 are rejected as being indefinite under 35 U.S.C. §112, 2nd paragraph. Applicants believe the amendment to claims cures these deficiencies.

Relevant Art of Record

The Examiner list the following references as relevant art of record:

U.S. Patent No. 7,345,053 to Garvey;

U.S. Patent No. 6,165,509 to Hoffman et al.;

U.S. Patent No. 6,416,834 to Fuller;

U.S. Patent No. 6,953,560 to Castro et al.;

U.S. Patent No. 6,759,129 to Fukushi;

U.S. Patent No. 7,056,550 to Davila et al.; and

U.S. Patent No. 6,270,779 to Fitzhugh et al..

Applicants respectfully submit that none of these references can anticipate or render obvious any of claims 1-11, 13 and 27 because none of these references, either alone or in combination, describe or suggest: (1) a coating comprising a fluorinated polymer and a biologically beneficial polymer as defined in claim 1, and (2) a biologically beneficial polymer being conjugated to a biologically active agent. All of these features are recited, directly or indirectly, in each of the claims under consideration.

Conclusion

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 07-1850. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 07-1850. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorize payment of any such extensions fees to Deposit Account No. 07-1850.

Respectfully submitted,

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